

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

JILLIAN SPINDEL,

Plaintiff,

V.

No. 2-22-cv-3106-GRB-AYS

TERRY D. AMARAT, M.D., JON-PAUL
DIMAURO, M.D., NORTHWELL HEALTH
LONG ISLAND JEWISH MEDICAL CENTER,
DEPUY SYNTHES PRODUCTS, INC.,
DEPUY SYNTHES SALES, INC.,
DEPUY SYNTHES SPINE, INC. and
JOHNSON & JOHNSON, INC.,

Defendants.

DEPUY'S ANSWER TO PLAINTIFF'S COMPLAINT AND AFFIRMATIVE DEFENSES

Defendants DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. (collectively “DePuy”) for their Answer to Plaintiff’s Complaint state as follows and assert the following affirmative defenses:

THE PARTIES

1. Plaintiff, JILLIAN SPINDEL (hereinafter, “Plaintiff”) is an individual who resides in Suffolk County, New York.

ANSWER: DePuy admits that Plaintiff Jillian Spindel is a New York resident [*see* DePuy’s Notice of Removal, ECF No. 1].

2. That at all times herein mentioned, Defendant TERRY D. AMARAT, M.D., was, and is a physician duly licensed by the State of New York and held himself out to the general public, and in particular to Plaintiff, as a physician offering professional services, medical care and treatment.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 2 and therefore denies the same.

3. That at all times herein mentioned TERRY D. AMARAT, M.D., had his principal place of business at Northwell Health Long Island Jewish Medical Center 270-05 76th Avenue, New Hyde Park, New York 11040.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 3 and therefore denies the same.

4. That at all times herein mentioned, Defendant JON-PAUL DIMAURO, M.D., was, and is a physician duly licensed by the State of New York and held himself out to the general public, and in particular to Plaintiff, as a physician offering professional services, medical care and treatment.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 4 and therefore denies the same.

5. That at all times herein mentioned JON-PAUL DIMAURO, M.D. had his principal place of business at Northwell Health Long Island Jewish Medical Center 270-05 76th Avenue, New Hyde Park, New York 11040.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 5 and therefore denies the same.

6. That at all times herein mentioned, Defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER, was and is a medical facility located at 270-05 76th Avenue, New Hyde Park, New York 11040.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 6 and therefore denies the same.

7. That at all times herein mentioned, Defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER was and is a New York domestic not-for profit corporation with its principal place of business located at 270-05 76 Avenue, New Hyde Park, New York 11040.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 7 and therefore denies the same.

8. At all times herein mentioned, defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER owned, operated, controlled, and managed a medical facility pursuant to the laws of the State of New York for the care of the sick, known as NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER located at 270-05 76 Avenue, New Hyde Park, New York 11040 which provided personnel, including doctors, nurses, attendants and others for the care and treatment of its patients and which held itself out to the public as furnishing treatment facilities where patients, including Plaintiff, could be treated for various ailments.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 8 and therefore denies the same.

9. That at all times herein mentioned, Defendant, NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER held itself out to the public and more particularly to the plaintiff as utilizing and employing medical personnel possessing the proper degree of learning and skill and it undertook to use reasonable care and diligence in the treatment of Plaintiff, JILLIAN SPINDEL.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 9 and therefore denies the same.

10. That at all times herein mentioned, defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER rendered services to Plaintiff in the nature of medical diagnosis and treatment.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 10 and therefore denies the same.

11. That at all times herein mentioned, defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER by and through its employees, personnel, physicians, nurses, assistants, agents and/or partners, was managing the medical care of plaintiff.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 11 and therefore denies the same.

12. That at all times herein mentioned, defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER by and through its employees, personnel, physicians, nurses, assistants, agents and/or partners, controlled the medical care of plaintiff.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 12 and therefore denies the same.

13. That at all times herein mentioned, defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER by and through its employees, personnel, physicians, nurses, assistants, agents and/or partners, supervised the care of Plaintiff.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 13 and therefore denies the same.

14. That at all times herein mentioned, defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER by and through its employees, personnel, physicians, nurses, assistants, agents and/or partners, maintained the care of Plaintiff.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 14 and therefore denies the same.

15. At all pertinent times, defendant Terry D. AMARAT, M.D., was an employee, agent, and/or independent contractor of Defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 15 and therefore denies the same.

16. At all pertinent times, Defendant JON-PAUL DIMAURO, M.D. was an employee, agent, and/or independent contractor of Defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 16 and therefore denies the same.

17. At all pertinent times, Defendant Terry D. AMARAT, M.D. and defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER stood in such a relationship with each other in their care and treatment of Plaintiff JILLAN SPINDEL, as to make Defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER liable for the acts and omissions of defendant Terry D. AMARAT, M.D.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 17 and therefore denies the same.

18. At all pertinent times, Defendant JON-PAUL DIMAURO, M.D. and defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER stood in such a relationship with each other in their care and treatment of Plaintiff JILLIAN SPINDEL, as to make Defendant NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER liable for the acts and omissions of defendant JON-PAUL DIMAURO, M.D.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 18 and therefore denies the same.

19. Defendant DEPUY SYNTHES PRODUCTS, INC. is a Delaware corporation with a principal place of business located at One DePuy 1302 Wrights Lane East, West Chester, PA 19380.

ANSWER: DePuy admits that DePuy Synthes Products, Inc. is a Delaware Corporation with its principal place of business located in Massachusetts. DePuy denies the remainder of

paragraph 19, which incorrectly identifies DePuy Synthes Products, Inc.'s principal place of business.

20. DEPUY SYNTHES SALES, INC. is a Delaware Corporation with a principal place of business located at One Depuy 1302 Wrights Lane East, West Chester PA 19380.

ANSWER: DePuy admits that DePuy Synthes Sales, Inc. is a Massachusetts Corporation with its principal place of business located in Massachusetts. DePuy denies the remainder of paragraph 20, which incorrectly identifies DePuy Synthes Sales, Inc.'s principal place of business and state of incorporation.

21. DePuy Synthes Spine, is a Delaware Corporation with a principal place of business located at 1302 Wrights Lane East, West Chester, PA 19380

ANSWER: DePuy denies that "DePuy Synthes Spine" is an independent and existing business entity. It is not a proper party to this case and Plaintiff's counsel has agreed to dismiss it from this action.

22. JOHNSON AND JOHNSON INC. is a foreign business corporation with a principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

ANSWER: DePuy admits that Johnson & Johnson is a New Jersey corporation with its principal place of business in New Jersey. Responding further, DePuy states that Johnson & Johnson is a holding company, is not a proper party to this case, and Plaintiff's counsel has agreed to dismiss it from this action.

23. “DEPUY SYNTHES”, including defendants DEPUY SYNTHES PRODUCTS INC, DEPUY SYNTHES SALES, INC and DEPUY SYNTHES SPINE INC, is the orthopedics company / division of JOHNSON & JOHNSON INC.

ANSWER: DePuy admits that Johnson & Johnson (incorrectly named as “Johnson & Johnson, Inc.”) is a holding company and that DePuy Synthes Sales and DePuy Synthes Products are indirect subsidiaries involved in the design, manufacture, and sale of medical devices, among other business activities. DePuy denies all remaining allegations contained in paragraph 23.

24. Defendants DEPUY SYNTHES PRODUCTS INC., DEPUY SYNTHES SALES, Inc. DEPUY SYNTHES SPINE INC., and JOHNSON & JOHNSON INC. (hereinafter “DEPUY defendants”) regularly do and/or solicit business within the State of New York.

ANSWER: DePuy admits that DePuy Synthes Sales and DePuy Synthes Products do business in the state of New York. DePuy further states that Johnson & Johnson (incorrectly named as “Johnson & Johnson, Inc.”) is a holding company and does not design, manufacture, or sell medical devices. DePuy denies the remaining allegations in paragraph 24.

25. The DEPUY defendants have conducted substantial business and derived, substantial revenue from and within the State of New York. Defendant expected or should have expected its business activities to have consequences with the State of New York as it was engaged in conduct and regularly transacted business in the State of New York.

ANSWER: DePuy admits that DePuy Synthes Sales and DePuy Synthes Products do business in the state of New York. DePuy further states that Johnson & Johnson (incorrectly named as “Johnson & Johnson, Inc.”) is a holding company and does not design, manufacture, or sell medical devices. DePuy denies the remaining allegations in paragraph 25.

26. The DEPUY defendants expected or should have expected its business activities to have consequences with the State of New York as it was engaged in conduct and regularly transacted business in the State of New York.

ANSWER: Paragraph 26 contains a bare legal conclusion to which no response is necessary. To the extent that a response is required, DePuy states that DePuy Synthes Sales and DePuy Synthes Products do business in the state of New York. DePuy denies all remaining allegations contained in paragraph 26.

27. The DEPUY defendants promote themselves as global technology leaders in medical and surgical products.

ANSWER: DePuy admits that it is a global leader in the design, manufacture, and sale of medical devices and surgical products.

28. The DEPUY defendants designed manufactured, tests, promoted, sold and labeled medical products, instrumentation, and hardware that was used on the plaintiff during surgery on July 15, 2020 (hereinafter “product” or “products”).

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 28 and therefore denies the same. DePuy denies that it caused Plaintiff’s injuries or is liable to Plaintiff in any way.

29. A DEPUY spinal system was used in plaintiff’s surgery on July 15, 2020.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 29 and therefore denies the same. DePuy denies that it caused Plaintiff’s injuries or is liable to Plaintiff in any way.

30. Upon information and belief, the products used in plaintiff's surgery include DuPuy Expedium, cobalt chromium rods, uniaxial pedicle screws, Dupuy Spine screws, Rod Viper Straight, and/or other or associated devices, instrumentation and hardware that was used on the plaintiff during surgery on July 15, 2020.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 30 and therefore denies the same. DePuy denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

31. Upon information and belief, the DEPUY Expedium system was used in plaintiff's surgery on July 15, 2020.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 31 and therefore denies the same. DePuy denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

33. The aforementioned products, is used in hospitals for surgeries, including posterior spinal fusions.

ANSWER: DePuy admits only that its Expedium Spine System can be safely used by surgeons to perform spinal fusion surgeries. DePuy lacks knowledge or information sufficient to form a belief as to the specific devices used or implanted in Plaintiff's surgeries, and therefore denies the same. DePuy denies any remaining factual allegations contained in paragraph 33.¹

¹ Plaintiff's Complaint omits paragraph 32. DePuy's Answer and Affirmative Defenses follows the same numbering.

34. The DEPUY defendants have promoted and continues to promote the products used in plaintiff's surgery on July 15, 2020 as safe and safer than other similar products.

ANSWER: DePuy admits only that its Expedium Spine System can be safely used by surgeons to perform spinal fusion surgeries and that DePuy has promoted this safe use in accordance with the device's Instructions for Use. DePuy lacks knowledge or information sufficient to form a belief as to the specific devices used or implanted in Plaintiff's surgeries and therefore denies the same. DePuy denies any remaining factual allegations contained in paragraph 34.

35. The DEPUY defendants use prominent websites directed at consumers to create demand for their use of its product by patients who consult surgeons.

ANSWER: DePuy admits that its spine products are prescription medical devices that may only be prescribed and implanted by a licensed surgeon. DePuy denies the remaining allegations in paragraph 35.

36. The DEPUY defendants' promotional materials misrepresented the safety, effectiveness, and utility of the aforementioned product and the aforementioned defendants failed to provide complete timely, and accurate information to the government, hospital, physicians, and consumers with respect to dangerous defects associated with its product.

ANSWER: DePuy denies the allegations contained in paragraph 36. Responding further, DePuy denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

37. The DEPUY defendants do not provide adequate warnings to physicians and patients about the risks and complications associated with the use of its product.

ANSWER: DePuy denies the allegations contained in paragraph 37. Responding further, DePuy denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

38. The DEPUY defendants have not done, nor sponsored, any testing as to the aforementioned product(s).

ANSWER: DePuy denies the allegations contained in paragraph 38. Responding further, DePuy denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

39. The DEPUY defendants have failed to report to governmental agencies an accurate and complete illustration of the complications associated with the uses of said products.

ANSWER: DePuy denies the allegations contained in paragraph 39. Responding further, DePuy denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

40. The DEPUY defendants have over-promoted the aforementioned product to hospitals, physicians and the public, including potential consumers, combined with minimizing the risks and/or complications associated with the use of the aforementioned product.

ANSWER: DePuy denies the allegations contained in paragraph 40. Responding further, DePuy denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

41. Use of the DEPUY defendants' product(s) in surgery presents considerable risks of physical complications, pain and injuries following surgery as well as risk of future surgeries.

ANSWER: DePuy denies the allegations contained in paragraph 41. Responding further, DePuy denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

42. The DEPUY defendants do not adequately train physicians nor proctor them properly on the use of its system, thereby inducing them to cause complications and injuries, which would be avoided in the hands of properly trained physicians.

ANSWER: DePuy denies the allegations contained in paragraph 42. Responding further, DePuy denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

43. Due to design defects, the DEPUY defendants' product(s) have malfunctioned during and after surgeries, causing injury, requiring additional surgeries and procedures to deal with the complications from malfunction.

ANSWER: DePuy denies the allegations contained in paragraph 43. Responding further, DePuy denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

44. The aforementioned product(s) was/were defective and its application and implantation in the plaintiff's body caused severe injuries as a result of product failure.

ANSWER: DePuy denies the allegations contained in paragraph 44. Responding further, DePuy denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

45. At all times hereinafter mentioned the DEPUY defendants had a duty to properly design, manufacture, compound, test, inspect, package, distribute, market, examine, prepare for use and sell the aforementioned product(s). The DEPUY defendants have obtained and continue to maintain approval of the uses of the product(s) from the Food and Drug Administration and/or other governmental agencies, but it does so by failing to fully inform them of its knowledge of risk and complications associated with the use of its product(s).

ANSWER: Paragraph 45 contains a bare legal conclusion to which no response is necessary. To the extent that a response is required, DePuy states that its medical devices are approved or cleared by the U.S. Food & Drug Administration, which has deemed them safe and effective. DePuy denies the allegations contained in paragraph 45.

46. The DEPUY defendants had specific knowledge and awareness of the dangers of the aforementioned product(s) and it knew or should have known that there were safety modalities commercially available that could have greatly diminished or eliminated some of these risks, yet the DEPUY defendants chose not to take such safety measures.

ANSWER: DePuy denies the allegations contained in paragraph 46. Responding further, DePuy denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

AS FOR THE FIRST CAUSE OF ACTION AGAINST DEFENDANTS TERRY D. AMARAT, M.D., JON-PAUL DIMAURO, M.D. AND NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER HOSPITAL: MEDICAL MALPRACTICE

47. Plaintiff incorporates by reference each proceeding paragraphs as though set forth fully at length herein.

ANSWER: DePuy hereby incorporates its responses to all prior allegations.

48. That at all times herein mentioned, the Defendants, TERRY D. AMARAT, M.D., JON-PAUL DIMAURO, M.D. AND NORTHWELL HEALTH LONG ISLAND JEWISH MEDICAL CENTER HOSPITAL their agents, servants, partners and/or employees undertook and agreed to render medical care to the Plaintiff herein and did render medical care and treatment in or around July 15, 2020, and at times prior and subsequent thereto.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 48 and therefore denies the same.

49. That the aforementioned defendants, individually, jointly and severally and through their agents, servants, employees and/or associates were responsible for the proper, adequate and necessary medical care and treatment of the decedent and that by virtue of the above, the defendants were negligent and careless and failed to conform with known and accepted customs, practices, methods, standards and procedures so as to avoid and prevent the aforesaid occurrence.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 49 and therefore denies the same.

50. The medical care rendered by the aforementioned defendants, their agents, servants, partners and/or employees were rendered in a negligent, careless, and unskilled manner, which departed and deviated from the accepted standards of medical care.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 50 and therefore denies the same.

51. The Defendants' their agents, servants, partners and/or Plaintiff were negligent in that they negligently and carelessly failed to heed Plaintiff's condition; negligently and carelessly departed from good and accepted medical practices and procedures rendered for and on behalf of Plaintiff; performed contraindicated procedures; failed and neglected to exercise that degree of care caution, prudence, skill, ability, professional knowledge and training generally possessed by physicians and medical care facilities.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 51 and therefore denies the same.

52. That said occurrence was due to the carelessness and professional negligence the defendants, their agents, servants, partners, and/or employees for failure to timely diagnose and treat Plaintiff's medical condition and treat the Plaintiff with the accepted and proper medical management and without any fault or lack of care on the part of the Plaintiff.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 52 and therefore denies the same.

53. As a result of the aforementioned negligence and the careless treatment rendered by the defendants, the Plaintiff was caused to sustain severe, serious and permanent injuries that had rendered her sick, sore, lame and disabled.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 53 and therefore denies the same

54. That during and following the aforementioned surgical procedure the plaintiff suffered severe and personal injuries, caused to endure unnecessary pain and suffering, was caused to suffer severe physical pain and mental anguish, further medical and surgical procedures, and sustain injuries and scarring.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 54 and therefore denies the same.

55. The aforesaid medical, nursing care, treatments, and services were rendered carelessly, unskillfully, negligently, and not in accordance with accepted standards of medical nursing care, treatment, and services in the community.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 55 and therefore denies the same.

56. The aforementioned defendants, their agents, servants, partners and/or employees negligently and carelessly departed from good and accepted medical practices and procedures rendered for and on behalf of Plaintiff.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 56 and therefore denies the same.

57. The aforesaid incident and its resulting injures [*sic*] were caused or permitted by the careless and negligent conduct of the aforementioned defendants, their agents, servants and/or employees.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 57 and therefore denies the same.

58. Said occurrence and resulting injuries occurred without any fault of wrongdoing on the part of the Plaintiff contributing thereto.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 58 and therefore denies the same.

59. The aforesaid occurrence and its resulting injuries were caused or permitted by the medical malpractice of the aforementioned Defendants herein.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 59 and therefore denies the same.

60. This action falls within one or more of the exceptions set forth in CPLR 1602, and as such the defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 60 and therefore denies the same.

61. Pursuant to CPLR §1602(2)(iv), Defendants are jointly and severally liable for all of the Plaintiff's damages, including but not limited to Plaintiff and Plaintiff's non-economic loss, irrespective of the provisions of CPLR § 1601, by reason of the fact that Defendants owed Plaintiff a non-delegable duty of care.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 61 and therefore denies the same.

62. Pursuant to CPLR § 1602(2)(iv), Defendants are jointly and severally liable for all Plaintiff's damages, including but not limited to, Plaintiff's non-economic loss, irrespective of the provisions of CPLR § 1601, by reason of the fact that said Defendants are vicariously liable for the negligent acts and omissions of the servants, agents, affiliated, physicians, surgeons and/or employees.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 62 and therefore denies the same.

63. Pursuant to CPLR § 1602(7), Defendants are jointly and severally liable for all of Plaintiff's damages, including but not limited to Plaintiff's non-economic loss, irrespective of the provisions of CPLR § 1601, by reason of the fact that said Defendants acted with reckless disregard for the safety of others.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 63 and therefore denies the same.

64. By reason of the foregoing, Plaintiff has been damaged in the amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

ANSWER: Paragraph 64 contains legal conclusions to which no response is required. DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 64 and therefore denies the same.

AS AND FOR A SECOND CAUSE OF ACTION: VICARIOUS LIABILITY

65. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

ANSWER: DePuy hereby incorporates its responses to all prior allegations.

66. Defendants, prior to the granting or renewing or privileges or employment of defendants, residents and others involved in Plaintiff's care, failed to investigate the qualifications, competence, capacity, abilities and capabilities of said Defendants, physicians, residents, and other

employees including, but not limited to, obtaining the following information: patient grievances, negative health care, outcomes, incidents and injuries to patients, medical malpractice actions commenced against said persons, including the outcome thereof, any history of association, privilege and/or practice at other institutions, any discontinuation of said association, employment privilege and/or practice at said institution, and any pending professional misconduct proceedings in this State or in any other state, the substance of the allegations and such proceedings and any additional information concerning such proceedings and the findings of such proceedings, and failed to make sufficient inquiry of the doctors, and/or employee in institutions which should and did have information relative to the capacity, capability, ability and competence of said persons rendering treatment.

ANSWER: DePuy does not employ any of the surgeons or healthcare providers who performed Plaintiff's surgery or provided healthcare services and, therefore, is not a plausible target for any claim of vicarious liability. Accordingly, DePuy does not interpret paragraph 66 as alleging any facts against DePuy and therefore denies any factual allegations for lack of knowledge or information. To the extent there are any factual allegations in this paragraph alleged against DePuy, DePuy denies them. DePuy further denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

67. Had the Defendants made the above-described inquiry or, in the alternative, had the defendants reviewed and analyzed the information obtained in a proper manner, privileges and/or employment would not have been granted and/or renewed.

ANSWER: DePuy does not interpret paragraph 67 as alleging any facts against DePuy and therefore denies any factual allegations for lack of knowledge or information. To the extent

there are any factual allegations in this paragraph alleged against DePuy, DePuy denies them. DePuy further denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

68. By reason of the Defendants' failure to meet the aforementioned obligation, Plaintiff was treated by doctors, and/or other employees, who were lacking the requisite skills, abilities, competence and capacity, as a result of which Plaintiff sustained severe injuries and complications.

ANSWER: DePuy does not interpret paragraph 68 as alleging any facts against DePuy and therefore denies any factual allegations for lack of knowledge or information. To the extent there are any factual allegations in this paragraph alleged against DePuy, DePuy denies them. DePuy further denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

69. By reason of the above, Plaintiff sustained great pain, agony, injury, suffering, disability, hospitalization, as well as mental anguish and emotional distress.

ANSWER: DePuy does not interpret paragraph 69 as alleging any facts against DePuy and therefore denies any factual allegations for lack of knowledge or information. To the extent there are any factual allegations in this paragraph alleged against DePuy, DePuy denies them. DePuy further denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

70. By reason of the foregoing, Plaintiff, has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

ANSWER: Paragraph 70 contains legal conclusions to which no response is required. DePuy does not interpret paragraph 70 as alleging any facts against DePuy and therefore denies any factual allegations for lack of knowledge or information. To the extent there are any factual

allegations in this paragraph alleged against DePuy, DePuy denies them. DePuy further denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

**AS FOR A THIRD CAUSE OF ACTION AGAINST ALL DEFENDANTS:
LACK OF INFORMED CONSENT**

71. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

ANSWER: DePuy hereby incorporates its responses to all prior allegations.

72. That at no time prior to the occurrence, nor on the date of the occurrence was the plaintiff ever advised, either orally or in writing, of the possible risks and dangers, nor the possibility of permanent damage to her body with regard to the care being rendered to her, nor was she advised that she may suffer severe or personal damages, and had the defendants or any of their agents, servants, employees and/or associates informed or advised the decedent of the possible risks and dangers involved, the decedent would not have been lulled into a false sense of security and would never have consented to the treatment being rendered to her.

ANSWER: DePuy is not a healthcare provider and played no role in obtaining Plaintiff's informed consent for her surgery or any other healthcare services that were rendered and, therefore, it is not a plausible target for any claim of lack of informed consent. Accordingly, DePuy does not interpret paragraph 72 as alleging any facts against DePuy and therefore denies any factual allegations for lack of knowledge or information. To the extent there are any factual allegations in this paragraph alleged against DePuy, DePuy denies them. DePuy further denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

73. Defendants their agents, servants and employees, failed to inform Plaintiff or her legal representative of the reasonably foreseeable risks and benefits of, and alternatives to, the treatment proposed and rendered, which would have been disclosed by a reasonable medical practitioner in similar circumstances, in consequence of which defendants failed to obtain a [sic] informed consent thereto.

ANSWER: DePuy does not interpret paragraph 73 as alleging any facts against DePuy and therefore denies any factual allegations for lack of knowledge or information. To the extent there are any factual allegations in this paragraph alleged against DePuy, DePuy denies them. DePuy further denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

74. Reasonably prudent persons in the Plaintiff's position would not have consented to the treatment rendered, in connection with the Plaintiff's condition if they had been fully informed of the risks, hazards and alternatives connected with said procedures.

ANSWER: DePuy does not interpret paragraph 74 as alleging any facts against DePuy and therefore denies any factual allegations for lack of knowledge or information. To the extent there are any factual allegations in this paragraph alleged against DePuy, DePuy denies them. DePuy further denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

75. The failure to adequately and fully inform the Plaintiff of risks, hazards and alternatives of the medications prescribed and the treatment rendered in connection with the treatment of the plaintiff is a proximate cause of the injuries the Plaintiff sustained.

ANSWER: DePuy does not interpret paragraph 75 as alleging any facts against DePuy and therefore denies any factual allegations for lack of knowledge or information. To the extent

there are any factual allegations in this paragraph alleged against DePuy, DePuy denies them. DePuy further denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

76. As a consequence of the foregoing, there was no informed consent to the treatment rendered.

ANSWER: DePuy does not interpret paragraph 76 as alleging any facts against DePuy and therefore denies any factual allegations for lack of knowledge or information. To the extent there are any factual allegations in this paragraph alleged against DePuy, DePuy denies them. DePuy further denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

77. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

ANSWER: Paragraph 77 contains legal conclusions to which no response is necessary. DePuy does not interpret paragraph 77 as alleging any facts against DePuy and therefore denies any factual allegations for lack of knowledge or information. To the extent there are any factual allegations in this paragraph alleged against DePuy, DePuy denies them. DePuy further denies that it caused Plaintiff's injuries or is liable to Plaintiff in any way.

**AS A FOURTH CAUSE OF ACTION AGAINST DEPUY DEFENDANTS :
NEGLIGENCE**

78. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

ANSWER: DePuy hereby incorporates its responses to all prior allegations.

79. Defendants had a duty to individuals, including plaintiff, to exercise the care of an expert in all aspects of the formulation, manufacture, compounding testing, inspection, packaging, labeling distribution, marketing, and the sale of the Products.

ANSWER: Paragraph 79 contains legal conclusion to which no response is necessary. DePuy denies that breached any duties to Plaintiff, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way.

80. Defendants failed to exercise reasonable care in testing the product from its effects in ordinary and foreseeable users; and failed to disseminate to physicians accurate and truthful information concerning the effects of the product; thus physicians were not able to make informed choices concerning the use of the product.

ANSWER: DePuy denies the allegations contained in paragraph 80.

81. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Product(s).

ANSWER: DePuy denies the allegations contained in paragraph 81.

**AS FOR A FIFTH CAUSE OF ACTION AGAINST THE DEPUY DEFENDANTS:
STRICT PRODUCTS LIABILITY**

82. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

ANSWER: DePuy hereby incorporates its responses to all prior allegations.

83. At all relevant times, the Defendants were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling the product(s).

ANSWER: DePuy admits that it designs, manufactures, promotes, markets and sells medical devices. DePuy denies any remaining allegations contained in paragraph 83.

84. The product(s) was defective and unreasonably dangerous to consumers.

ANSWER: DePuy denies the allegations contained in paragraph 84.

85. At all times mentioned in this Complaint, the product(s) was defective and/or unreasonably dangerous to Plaintiff and other foreseeable users at the time it left the control of the DEPUY Defendants.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies any remaining allegations contained in paragraph 85.

86. The product(s) is defective in its design or formulation in that when it left the hands of the DEPUY defendants its foreseeable risks exceed the benefits associated with its design and formulation and/or it was more dangerous than an ordinary consumer would expect.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies any remaining allegations contained in paragraph 86.

87. The foreseeable risks associated with the design or formation of the product include, but are not limited to, the fact that the design or formulation of the product is more dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies any remaining allegations contained in paragraph 87.

88. At all times material to this action, the product was expected to reach, and did reach consumers in the State of New York and throughout the United States, including the Plaintiff, without substantial change in the condition in which it was sold.

ANSWER: DePuy lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 88 and therefore denies the same. DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way.

89. The DEPUY defendants developed, marketed and distributed the product to the general public even after learning of the design and manufacturing defects that threatened the intended use of the product.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies any remaining allegations contained in paragraph 89.

90. The DEPUY defendants knew or should have known through testing, adverse event reporting, or otherwise, that the product created a high risk of bodily injury and serious harm.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 90.

91. The dangerous propensities of the products were known or scientifically knowable, through appropriate research and testing, to the DEPUY defendants at the time Defendants distributed, supplied, or sold the product, and not known to ordinary physicians who would be expected to use the product for their patients.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 91.

92. The product, as distributed, were defective and unreasonable dangerous inasmuch as the product were not accompanied by warnings and instructions that were appropriate and adequate to render the product reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of the product.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 92.

93. In order to advance the DEPUY defendants' own pecuniary interests, the DEPUY defendants proceeded with the manufacturing, the sale and distribution, and marketing of the product with knowledge that consumers would be exposed to serious danger.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 93.

94. At all times material to this action, the product was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the DEPUY defendants in a "defective" and unreasonably dangerous" condition at the time it was placed in the stream of commerce.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 94.

95. The DEPUY defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiff seeks recovery.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 95.

96. The DEPUY defendants knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of the product that cause the damages for which Plaintiff seeks recovery.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 96.

97. The reasonably foreseeable use of the product(s) involved substantial dangers not readily recognizable by the ordinary physician who used the product or the patient including Plaintiff.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 97.

98. The DEPUY defendants knew that the product was to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that the product were not properly prepared nor accompanied by adequate warnings of the dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 98.

99. Plaintiff's physicians did not know, nor had any reason to know, at the time of the use of DEPUY defendants' product(s), or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 99.

100. The above defects caused serious injury to Plaintiff when the product(s) was/were used in its intended and foreseeable manner, and in the manner recommended by the DEPUY Defendants and/or in a non-intended manner that was reasonably foreseeable.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 100.

101. In addition, at the time that the product left the control of the DEPUY Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the products utility.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 101.

102. As a direct and proximate result of the wrongful acts of the DEPUY Defendants, Plaintiff suffered severe injuries, and pain, suffering and damages which will continue for the foreseeable future.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 102.

103. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

ANSWER: Paragraph 103 contains legal conclusions to which no response is necessary. DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 103.

**AS AND FOR A SIXTH CAUSE OF ACTION AGAINST THE
DEPUY DEFENDANTS: FAILURE TO WARN**

104. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

ANSWER: DePuy hereby incorporates its responses to all prior allegations.

105. In the regular course of business, the DEPUY defendants designed, manufactured and sold the aforementioned product(s) to medical facilities, including the facility in which the plaintiff had surgery.

ANSWER: DePuy admits only that it designs, manufactures, and sells medical devices. DePuy lacks information or knowledge sufficient to form a belief as to the remaining allegations in paragraph 105 and therefore denies the same.

106. At the time of design, manufacture and sale of the product(s) and more specifically the time of the plaintiff's July 15, 2020 spinal fusion surgery, the product(s) were defective and unreasonably dangerous when put to their intended and reasonably anticipated use.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 106.

107. Furthermore, the aforementioned products were not accompanied by proper warnings regarding significant adverse consequences associated with its use.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 107.

108. The DEPUY defendants failed to provide any warnings, labels, or instruction of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the products involved significant dangers not readily obvious to the ordinary user of the products. Defendants failed to warn of the known or knowable injuries associated with malfunction of the product(s).

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 108.

109. Upon information and belief, the dangerous and defective conditions in the product(s) existed at the time they were delivered by the manufacturer to the distributor. At the time the plaintiff had surgery, the product(s) were in the same condition as when manufactured, distributed, and sold.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 109.

110. Plaintiff suffered the aforementioned serious physical and mental injuries as a direct result of the DEPUY defendants' failure to warn.

ANSWER: DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 110.

111. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

ANSWER: Paragraph 111 contains legal conclusions to which no response is necessary. DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way.

**AS AND FOR A SEVENTH CAUSE OF ACTION AGAINST DEPUY SYNTHES:
BREACH OF IMPLIED AND EXPRESS WARRANTY**

112. Plaintiff incorporates by reference each preceding paragraph as though set forth fully at length herein.

ANSWER: DePuy hereby incorporates its responses to all prior allegations.

113. The DEPUY defendants made express warranties of safety to the buyers and consumers of the products utilized during Plaintiff's surgery, upon which the buyers and users, as agents of Plaintiff relied, to his detriment, the Defendants expressly represented to the plaintiff (and to the consumers and the medical community) that the product(s) was safe, efficacious, and fit for its intended purposes, that it was of merchantable quality, that it did not produce any unwarned-of dangerous side effects, and that it was adequately tested.

ANSWER: DePuy admits that it truthfully and legally markets its medical devices as safe and effective, consistent with each device's approval or clearance by the U.S. Food & Drug Administration. DePuy denies that it offered any express warranty to Plaintiff, her surgeon, or anyone else. Responding further, DePuy states that its medical devices are safe, denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 113.

114. The DEPUY Defendants in connection with its business activities aforementioned, warranted and represented expressly that said product(s) was safe in connection with its uses and further that same was of merchantable quality.

ANSWER: DePuy denies that it offered any express warranty to Plaintiff, her surgeon, or anyone else. Responding further, DePuy states that its medical devices are safe, denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 114.

115. Plaintiff and her physicians relied on the skill and judgment of the Defendant and its representation and warranties aforementioned in connection with the use of said product/device.

ANSWER: DePuy denies that it offered any express warranty to Plaintiff, her surgeon, or anyone else. Responding further, DePuy states that its medical devices are safe, denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 115.

116. Said representations and warranties aforementioned were false, misleading and inaccurate in that said product/device, when put to the test, was and proved to be unsound and unsuitable for the purposes for which it was intended and utilized and were unsafe, dangerous, improper and not of merchantable quality.

ANSWER: DePuy denies that it offered any express warranty to Plaintiff, her surgeon, or anyone else. Responding further, DePuy states that its medical devices are safe, denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 116.

117. Defendants were in breach of express warranty.

ANSWER: DePuy denies that it offered any express warranty to Plaintiff, her surgeon, or anyone else. Responding further, DePuy states that its medical devices are safe, denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 117.

118. DUPUY Defendants impliedly represented that said product(s) and its part were safe and of merchantable quality and fit for the ordinary purposes for said products were to be used.

ANSWER: DePuy admits that it truthfully and legally markets its medical devices as safe and effective, consistent with each device's approval or clearance by the U.S. Food & Drug Administration. DePuy denies that it offered or created any implied warranty under New York law or any other state law that may be deemed to apply. Responding further, DePuy states that its medical devices are safe, denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 118.

119. The said representations and warranties aforementioned were false, misleading, and inaccurate in that said product/device, when put to the test of actual wear, were and proved to be unsound and unsuitable for the purposes for which the same were intended and utilized and were unsafe, dangerous, improper and not of merchantable quality.

ANSWER: DePuy denies that it offered or created any implied warranty under New York law or any other state law that may be deemed to apply. Responding further, DePuy states

that its medical devices are safe, denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 119.

120. The DEPUY Defendants were in breach of implied warranties.

ANSWER: DePuy denies that it offered or created any implied warranty under New York law or any other state law that may be deemed to apply. Responding further, DePuy states that its medical devices are safe, denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 120.

121. That the aforementioned product(s) were defective and unfit for their intended purpose and plaintiff's and/or his physicians did not receive the goods as warranted.

ANSWER: DePuy denies that it offered or created any implied warranty under New York law or any other state law that may be deemed to apply. Responding further, DePuy states that its medical devices are safe, denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 121.

122. That as a result of relying upon defendants' skill, representations and warranties the plaintiff was injured.

ANSWER: DePuy denies that it offered or created any implied warranty under New York law or any other state law that may be deemed to apply. Responding further, DePuy states that its medical devices are safe, denies that its medical devices are defective or unreasonably

dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 122.

123. That aforesaid occurrences and resulting injuries to the plaintiff were not due to any fault or wrongdoing on the part of the plaintiff.

ANSWER: DePuy denies that it offered or created any implied warranty until New York law or any other state law that may be deemed to apply. Responding further, DePuy states that its medical devices are safe, denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 123.

124. That during and following the aforementioned surgical procedure the plaintiff suffered severe and personal injuries, caused to endure unnecessary pain and suffering, was caused to suffer severe physical pain and mental anguish, further medical and surgical procedures, and sustain injuries and scarring.

ANSWER: DePuy states that it lacks knowledge or information sufficient to form a belief as to the allegations contained in paragraph 124, and therefore denies these allegations. Responding further, DePuy states that its medical devices are safe, denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way.

125. The aforesaid occurrence and/or resulting injuries to the plaintiff were due to the carelessness, recklessness, and negligence of the DEPUY Defendants in the design, manufacture, production, distribution, assembly, repair and service of the aforementioned device.

ANSWER: DePuy denies that it offered or created any implied warranty until New York law or any other state law that may be deemed to apply. Responding further, DePuy states that its medical devices are safe, denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way. DePuy denies all remaining allegations contained in paragraph 125.

126. This action falls within one or more of the exceptions set forth in CPLR § 1602, and as such the defendants are jointly and severally liable pursuant to the exceptions set forth in Article 16 of the CPLR.

ANSWER: Paragraph 126 contains legal conclusions to which no response is necessary. To the extent a response is deemed required, DePuy denies all allegations contained in paragraph 126.

127. By reason of the foregoing, Plaintiff has been damaged in an amount that exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction in this matter.

ANSWER: Paragraph 127 contains legal conclusions to which no response is necessary. DePuy denies that its medical devices are defective or unreasonably dangerous, denies that it caused Plaintiff's injuries, and denies that it is liable to Plaintiff in any way.

SEPARATE DEFENSES

DePuy also asserts the following separate defenses. By alleging the separate defenses set forth below, DePuy is not in any way agreeing or conceding that it has the burden of proof or the burden of persuasion on any of these issues.

FIRST SEPARATE DEFENSE

Plaintiff's Complaint fails, in whole or in part, to state a claim upon which relief may be granted.

SECOND SEPARATE DEFENSE

The injuries and damages claimed by Plaintiff, if any, were caused in whole or in part by the acts or omissions of persons over whom DePuy has no control or right of control.

THIRD SEPARATE DEFENSE

At all times mentioned herein, to the extent that Plaintiff was negligent, careless, and at fault, and conducted herself so as to contribute substantially to her alleged injuries and damages, said negligence, carelessness, and fault of Plaintiff bars in whole or in part the damages which Plaintiff seeks to recover herein.

FOURTH SEPARATE DEFENSE

Plaintiff knowingly and voluntarily assumed any and all risks associated with the use of the products at issue in this case, and such assumption of the risks bars in whole or in part the damages Plaintiff seeks to recover herein.

FIFTH SEPARATE DEFENSE

Plaintiff's alleged damages, if any, are barred in whole or in part by Plaintiff's failure to mitigate such damages.

SIXTH SEPARATE DEFENSE

Plaintiff's claims are barred, in whole or in part, because the product at issue was at all relevant times manufactured and sold consistent with available technology, scientific knowledge, and the state of the art, and in compliance with all federal, state, and local laws and regulations, and was accompanied by product information and warnings that were reasonable, full and adequate

and in accordance with FDA regulating requirements and the state of medical and scientific knowledge then in existence.

SEVENTH SEPARATE DEFENSE

If DePuy's products are unsafe in any way, they are unavoidably unsafe. Plaintiff's purported action is, therefore, barred by Comment k of § 402A of the Restatement (Second) of Torts and/or other applicable law.

EIGHTH SEPARATE DEFENSE

Even if there was negligence and/or breach of warranty on its part, which DePuy defendants expressly denies, such negligence and/or breach of warranty was not the proximate or producing cause of Plaintiff's alleged injuries or damages.

NINTH SEPARATE DEFENSE

Plaintiff's alleged injuries and damages attributable to the use of the products at issue in this case, if any, were not legally caused by the products at issue, but instead were legally caused by intervening and superseding causes or circumstances.

TENTH SEPARATE DEFENSE

If Plaintiff incurred any injuries or damages as a result of the use of the products at issue, which DePuy denies, such injuries or damages were due to an idiosyncratic or idiopathic reaction, or by an unforeseeable or pre-existing condition.

ELEVENTH SEPARATE DEFENSE

Plaintiff's claims and causes of action are preempted by Medical Device Amendments to the Federal Food, Drug & Cosmetic Act and the FDA regulations promulgated pursuant thereto.

TWELFTH SEPARATE DEFENSE

Plaintiff's causes of action are barred by the applicable statutes of limitation, statutes of repose, and/or doctrine of laches.

THIRTEENTH SEPARATE DEFENSE

Plaintiff's causes of action are barred by the doctrines of informed consent, release, and waiver.

FOURTEENTH SEPARATE DEFENSE

Plaintiff's causes of action are barred by the learned intermediary doctrine and/or the sophisticated user doctrine.

FIFTEENTH SEPARATE DEFENSE

DePuy did not make to Plaintiff nor did it breach any express or implied warranties and/or breach of any warranties created by law. To the extent that Plaintiff relies on any theory of breach of warranty, such claims are barred by applicable law and for lack of privity with DePuy and/or failure of Plaintiff's, or Plaintiff's representatives, to give timely notice to DePuy of any alleged breach of warranty. DePuy further specifically pleads as to any breach of warranty claim all defenses under the Uniform Commercial Code existing and which may arise in the future.

SIXTEENTH SEPARATE DEFENSE

Plaintiff's claims of product defects are barred by Sections 2, 4, and 6(c) and (d) of the Restatement (Third) of Torts: Products Liability.

SEVENTEENTH SEPARATE DEFENSE

Plaintiff's claims should be diminished in whole or in part in the amount paid to Plaintiff by any party or non-party with whom Plaintiff has settled or may settle.

EIGHTEENTH SEPARATE DEFENSE

Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

NINETEENTH SEPARATE DEFENSE

DePuy is entitled to, and claims the benefits of, all defenses and presumptions set forth in

or arising from any rule of law or statute in any state whose law is deemed to apply in this case, including but not limited to all defenses and presumptions available to DePuy under New York law.

TWENTIETH SEPARATE DEFENSE

Plaintiff's claims are barred by the equitable doctrine of estoppel.

TWENTY-FIRST SEPARATE DEFENSE

Plaintiff's alleged injuries are a result of pre-existing and/or unrelated medical conditions for which DePuy is not responsible.

TWENTY-SECOND SEPARATE DEFENSE

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

TWENTY-THIRD SEPARATE DEFENSE

Plaintiff is barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by Plaintiff without substantially impairing the usefulness or intended purpose of the product.

TWENTY-FOURTH SEPARATE DEFENSE

To the extent that the products at issue in this lawsuit were changed, altered, or modified after they left the control of the manufacturer, such change, alteration, or modification was the legal cause of Plaintiff's injuries, if any.

TWENTY-FIFTH SEPARATE DEFENSE

Plaintiff's product liability claims are barred because the benefits of the relevant products outweighed the risk.

TWENTY-SIXTH SEPARATE DEFENSE

To the extent that the laws of New York, and any other state whose law is deemed to apply in this case, permit punishment to be measured by the net worth or financial status of DePuy and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious, and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing punishment, allows punishment to be imposed based on lawful profits and conduct of DePuy in other states, and allows dissimilar treatment of similarly situated defendants, in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, the state laws and constitutional provisions of DePuy, and similar protections afforded by any other state whose law is deemed to apply in this case.

TWENTY-SEVENTH SEPARATE DEFENSE

DePuy is entitled to the protections and limitations afforded under New York's products liability laws and statutes.

TWENTY-EIGHTH SEPARATE DEFENSE

The product at issue was in compliance with all applicable codes, standards, regulations and specifications established by the United States and/or the State of Indiana, or by any agencies of the United States and/or the State of New York, and accordingly the product at issue is presumed to be non-defective.

TWENTY-NINTH SEPARATE DEFENSE

Any and all damages alleged in the Complaint may have been caused by misuse of the product, failure to use the product properly, or negligent use of the product.

THIRTIETH SEPARATE DEFENSE

The DEPUY defendants reserve the right to raise such further and additional defenses as may be available upon the facts to be developed in discovery and under other applicable substantive law.

JURY DEMAND

The DEPUY defendants demand a trial by jury on all issues so triable.

Dated: June 1, 2022

Respectfully submitted,

/s/ J.T. Larson

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*Attorneys for Defendants
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CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of June 2022, a copy of the foregoing was served on all parties by operation of the Court's ECF system.

/s/ J.T. Larson
